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Intensive Lifestyle (e)Support to Reverse Diabetes-2

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Abstract

Advanced diabetes-type-2 patients often have high insulin resistance. Over the years their insulin medication rises, which further increases their insulin resistance and glucose management problems.

A HINTc (High Intensity Nutrition, Training & coaching) pilot study was conducted with 11 insulin-dependent patients. Hybrid eHealth support was given, with electronic support plus a multi-disciplinary health support team.

Based on preliminary 12 week results, attractiveness and feasibility of the intervention were high: recommendation 9,0 out of 10 and satisfaction 9,1 out of 10. TAM (Technology Acceptance Model) surveys showed high usefulness, feasibility and intentions for future use. Acceptance and health behaviours were also reinforced by the rapid results (average 9% weight loss, 20% lower fasting glucose and 71% lower insulin medication, plus a 46% increase on the Quality of Life Physical Health dimension).

Our analysis supports three types of conclusions. First, patients' health literacy and quality of life improved strongly, both supporting healthier behaviours. Second, a virtuous cycle was started, helping patients reverse diabetes-2 progression. Third, a design analysis was conducted regarding service mix efficacy in relation to key requirements for designing ICT-enabled lifestyle interventions.

Keywords: Diabetes-2, eHealth, Lifestyle, Monitoring, Coaching, Blended Care, Service Design

1 Introduction

Our Western lifestyle plays a large role in the onset and progression of diabetes mellitus type 2 (Lim 2011). Insulin resistance has an important role in creating a vicious circle, where medication needs generally increase over time. Moreover, increasing blood glucose and insulin levels speed up the processes of weight gain, insulin resistance, inflammation, aging and comorbidity (like CVD, kidney failure, cancers, neuropathy and dementia) (Hotamisligil 2010). Hence, reducing insulin dependence and insulin resistance can be seen as an important therapeutic goal. This can be achieved with healthy lifestyle improvements.

Several lifestyle interventions have yielded improved outcomes in type 2 diabetes patients on insulin therapy, most notably: lower blood sugar and lower medication needs (Jenkins 2008; Esposito 2009). However, these are often highly controlled interventions. Moreover, the long-

term sustainability of behaviours is limited. The question is: can we do this on a more 'Do-It-Yourself' and e-Supported basis? This would have two advantages. First, since behaviour improvements are implemented within patients' lives, it improves the chance of sustained health behaviour (Simons 2013). Second, it is cheaper. Since 2010 the Health Coach Program has been used to improve lifestyle and metabolic outcomes (including reduced insulin needs for diabetes-2 patients), via eSupport, improved self-management and rapidly improved health behaviours (Simons 2010, Simons 2015). To promote rapid health results, a HINTc (High Intensity Nutrition, Training & coaching) intervention was developed for this patient population. The intervention combines improving health literacy with active behaviour change support.

This paper discusses preliminary results after 12 weeks, as part of a larger 50-week study. Our focus here regards feasibility and attractiveness of the HINTc e-supported lifestyle intervention, plus design lessons. Medical results will be discussed in another paper.

Research Question:

What are the feasibility and attractiveness of the HINTc e-supported lifestyle coaching program; and what are the effects on quality of life?

As part of the design analysis we address: efficacy of the service mix deployed in eSupported lifestyle interventions. We combine the 12-week results from our measurements with a design analysis based on an evaluation framework of requirements for ICT-enabled healthy lifestyle interventions.

2 Theory

The eSupported lifestyle program combines coach sessions with electronic dashboarding and self-management. Hybrid programs (face-to-face plus tele-support) have been indicated to be attractive for some time (Demark-Wahnefried 2008). Finding the right mix between offline and online contacts is an ongoing design research challenge (Pekmezi 2011). A hybrid or multi-channel service mix is recommended (Sperling 2009, Simons 2002, 2006, 2010, 2010b), combining electronic and face-to-face interactions. For example, face to face 'on site' coaching and training have as benefits: a richer service experience with the coach, with other participants and with a health focused 'service scape'; group support experiences (obtaining additional social support and co-creating service experiences together); learning from each other; health experiences in healthy food-, sports- and relaxation exercises. Disadvantages are: more (travel) time needed; less flexibility regarding when and where; and not everyone likes group sessions (Demark-Wahnefried 2007). Electronic and (semi-)automated coaching has as benefits: more time-efficient; more flexibility in when and where to have contact; very explicit monitoring of your own progress online; having status reports including 'next steps' commitments always online. Disadvantages are: the sensory-, emotional- and group experiences are more limited. Also, the 'service scape' in which people are immersed is only virtual, not physical. In summary, often a hybrid service mix has most to offer.

Key functionalities to increase health motivations and behaviours in this eSupported lifestyle program are (Simons 2010, 2014 and 2016):

- Daily logging of insulin and blood sugar levels: for close progress monitoring of the health coaches, physicians and participants themselves.
- Close cooperation with physicians, for rapid medication adjustments initially (avoiding dangerously low blood sugars when insulin dosage is not reduced rapidly enough in the first days), plus medical monitoring/coaching in the following weeks.
- A personal online health dashboard with graphs of progress towards adherence targets on the various health behaviours;
- Automated feedback on lifestyle aspects where relatively positive scores have been achieved (nutrition, physical activity, stress management or an overall score);
- (Tele)coaching by a health coach, generating online reports on progress towards adherence targets in the personal dashboard;
- The (tele)coaching sessions can be flexibly planned, based on convenience and participant preference: during in-clinic visits or phone based from home;
- Options to ask questions to the coach: via messaging within the dashboard or via email;
- Online schedule indicating upcoming events: group sessions, individual coach sessions (when and where), physical measurements, surveys;
- A micro-learning Health Quiz accessible via smartphone, mail and/or web;
- Reading materials in the mail;
- Weekly tips via email on health, motivation and self-management;
- Besides individual coaching, group sessions are also used in order to stimulate group support, mutual inspiration and encouragement, plus peer education.

If we look at the design challenge of persuasive technology (Fogg 2002, 2009) for health, it was theorized and tested elsewhere that this challenge is not just located in the ICT design, but also in the design of the overall service scape, including health effects and coach relationship (Simons 2014b). It should generate positive, mutually reinforcing service experiences across communication channels and activate long term health motivation and -behaviours, in order to deliver long term results. This is reflected in the following design evaluation framework for health improvement ICT solutions (Simons 2014), see Figure 1. It helps evaluate the impact of ICT-enabled interventions on health effectiveness, coaching performance and ICT value adding.

Figure 1 addresses three evaluation domains. Domain 1 'health effectiveness' not only includes health outcomes, but also health literacy ('as a user I know how to best serve my health'), health behaviours and health well-being (meaning health related quality of life (Ware 1998) and the Seligman (2012) dimensions of well-being related to health). Preferably, health interventions have broader and deeper impacts rather than narrow ones, since the former will improve health well-being more significantly. Experiencing larger health well-being impacts forms an important intrinsic motivator for health behaviours in the longer term.

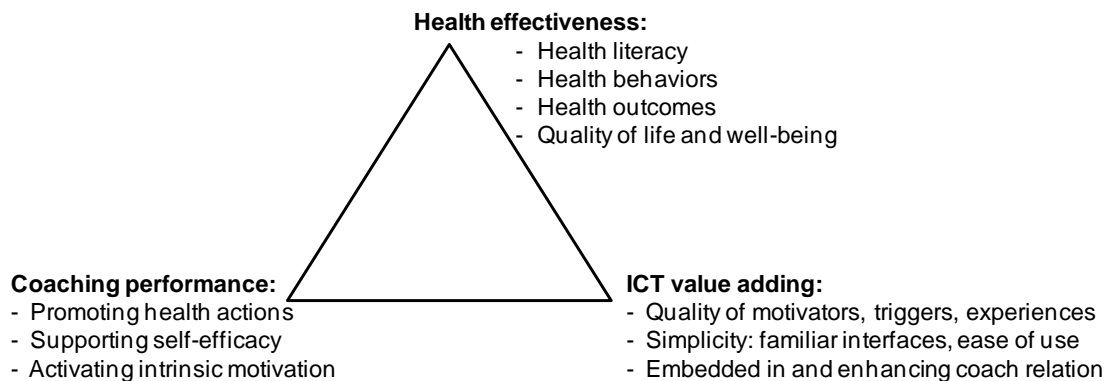


Figure 1: Basic requirements when designing ICT-supported healthy lifestyle interventions

Domain 2 ‘coaching performance’ not only includes promoting health actions (improving health readiness by moving from awareness to intentions to behaviours as in the HAPA (Health Action Process Approach) and i-change models, Schwarzer 2010, Wiedeman 2011), but also activating intrinsic motivations, and supporting users in their self-efficacy (their day-to-day attempts and successes to turn their health behaviour experiments into health wellness experiences, Lipke 2009).

Domain 3 ‘ICT value adding’ includes (Fogg 2002, Fogg 2009): value adding via high quality triggers, motivators and service experiences (which often involves using a mix of channels, each for their strengths – Demark-Wahnefried 2007, De Vries 2008, Sperling 2009, Simons 2004, Simons 2006), simplicity (which means using ICT interfaces that are mainstream for the user group, are attractive and easy to use - many initiatives underperform due to usability barriers, see Jimison 2008) and finally: embedding applications in an overall health provider or coach relationship (so that the meaning is enhanced of the coach relationship as well as the meaning of the data). For example, the foundations of coaching include ‘building rapport or relationship’, using different levels of listening based on empathy and intuition, see Starr 2008. This is best done by a person. This contrasts with the benefits (Simons 2010b) of automating processes of data logging and reporting.

3 Methods, Study Design, Intervention

This is a non-randomized, one arm, pilot intervention study of 12 weeks Sept-Nov 2015, plus effect measurement at 1 year of follow up; approved by the Leiden University Medical Center (LUMC) Ethics Board. The biomedical results will be addressed in a different paper. The study participants were 11 insulin-dependent Diabetes Mellitus Type-2 patients. Patients were volunteers, recruited by LUMC from the larger Leiden area in the Netherlands. They were 8 men and 3 women, ages 50-70 years (and 1 patient of 39 years old), with widely varying levels of education (mostly lower education levels) and of comorbidity.

Challenges regarding design of individual training schedules were posed by all the physical constraints in this group: 7 had significant movement restraints (knee- and hip-replacements,

cardiovascular blood flow constraints, stents), 5 had neuropathy, and 7 had cardiovascular disease. On average they had been diabetes-2 patient for more than 10 years and they were motivated for trying lifestyle improvements. TAM surveys (Technology Acceptance Model, Venkatesh 2000) were used at weeks 4 and 12 to assess intervention feasibility and attractiveness, along with user satisfaction evaluations. Besides, a standardised sit/stand test is used to assess strength (Csuka 1985) and an Astrand test (1976) for endurance.

Study inclusion criteria

- Type 2 diabetes mellitus treated by oral medication and insulin therapy.
- BMI ≥ 25 kg/m²
- Age 30-80 yrs
- Dutch language and basic computer competence (for use of email and web based dashboard)

Exclusion criteria

- Recent (< 3 months) myocardial infarction
- Uncontrolled blood pressure (SBP > 170 mmHg and/or DBP > 100 mmHg, 2 out of 3 measurements)
- Any chronic disease other than type 2 diabetes hampering participation (at the discretion of the investigator)
- Low motivation to participate (score 2 'weak' or 1 'very weak' on a 5-point scale).
- Alcohol consumption of more than 28 units per week at present or in the past
- Psychiatric disease (as defined by DSM-V)
- Claustrophobia
- Metal implants or other contraindications for MRI

The eSupported lifestyle intervention HINTc (High Intensity Nutrition, Training and coaching)

An extensive eSupported lifestyle program is offered, which combines coach sessions with electronic dashboarding and self-management, plus electronic health tips and a digital health quiz game. Intensive coaching is offered for 4 weeks with the purpose of generating self-propelling behaviours and capabilities. In week 1 a low calorie approach is taken to enable rapid alleviation of fatty liver conditions. The support in weeks 5-12 is more lightweight, with group sessions at the end of weeks 6, 8 and 12, weekly electronic tips and a digital health game.

As an umbrella overarching the personalized coaching per participant, the general lifestyle advice follows the guidelines of the Harvard Epidemiology and Nutrition Group for nutrition and physical activity, with specific modifications for diabetics. The guidelines are to increase intake of vegetables and low sugar fruits (each 2,5 servings/day or more), to choose whole grains instead of refined grains, to limit sugar and other high glycaemic load foods, to have one daily serving of nuts and/or legumes, to limit intake of red meat and processed meat, to limit intake

of trans and animal fats, and to have no more than 2 (male) or 1 (female) alcoholic beverages/day. Physical exercise guidelines are: at least 60 min/day moderate intensity activity (like walking or gardening) and at least 3x30 min/week intensive activity, which was also supported with group training sessions at the LUMC location three times per week (Borg level 12-14). Stress management guidelines are: relaxation exercises for >10 min/day.

4 Results

We discuss several types of results. We address answers to the research question: What are the feasibility and attractiveness of the HINTc e-supported lifestyle coaching program, including the positive feedback provided by the short term improvements in quality of life and physiology (insulin medication, blood sugar, physical stamina)? And we analyse efficacy of the service mix deployed in eSupported lifestyle interventions, following the framework of Figure 1 from Theory.

First, regarding attractiveness and feasibility, satisfaction and recommendation were not only high after 4 weeks (8,7 and 9,0 out of 10 respectively), but were even increased at the 12-week measurement: 9, 1 and 9,0 out of 10 respectively. This is in contrast with usual patterns where the initial enthusiasm of the first weeks wanes after 3 months. Moreover 'Health Related Quality of Life' as measured with the RAND SF-8 showed strong improvements over the 12-week period, especially on Physical Health (+46%): from 50.1 at start to 66.6 at week 4 to 73.1 at week 12, with 77 as the Dutch average. Mental Health went from 68.9 at start to 82.4 at week 4 to 80.6 at week 12, with 75 as the Dutch average. This further aided motivation to continue complying with these lifestyle guidelines. Added to the effects of self-efficacy and improved health, this motivated intrinsically and extrinsically. Qualitative feedback from the participants supports this interpretation: 'Have not felt so good in a long time' 'Now I understand much better how I can help myself' 'It is great to be less dependent on medication' 'I gained control' etc.

Second, there were physiological improvements in the first 12 weeks (average 9% weight loss, 20% lower fasting glucose, 13% lower HbA1C - an indicator for 3-month-averaged blood sugar levels - and 71% lower insulin medication). The majority of the insulin reduction even occurred in the first days and first week of the intervention. Biomedical details will be reported in a separate publication. However, it is clear that these rapid results helped motivate patients and provided positive feedback that they were on the right track. Besides, they started feeling more fit. The two measures for physical endurance (VO₂max: + 45%) and strength (30 sec sit/stand test: +23%) both improved over the 12-week period, including significant and motivating improvements in the first 4 weeks.

Third, the TAM (Technology Acceptance Model) user evaluations of week 4 and 12 shed some further light on patients' experience and appreciation of the intervention, see also Table 1.

TAM Construct	Week 4 Score (out of 7)	Week 12 Score (out of 7)
1. Usefulness	All items ≥ 6.5	All items ≥ 6.8

2. Effortless	-Lowest (5.4): Food guidelines 5.55: Daily physical exercise 5.55: Health Quiz	-Lowest (5.0): Health Quiz -& Lowest (5.0): Food/exercise logging in dashboard 5.3: Food guidelines
3. Opinion of social circle	All items ≥ 5.9	All items ≥ 6.3 ; except 'other patients': 5.4
4. Support	All items ≥ 5.8	All items ≥ 6.0
5. Affect	All items ≥ 6.5	All items ≥ 6.4
6. Ability	All items ≥ 6.2	All items ≥ 6.0
7. Trust	All items ≥ 6.2	All items ≥ 6.2
8. Valuation (e)Support elements 'What helped most to build health behaviours?'	Top 3 (6.9): Support Health Coaches, Personal Trainers, Physicians 6.6: Daily eLog sugar/insulin; Group sessions; Health Literacy -Lowest (5.4): Homework physical exercise -2 nd Low (5.5): Health Quiz	6.9: Personal Trainers 6.8: Health Literacy 6.7: Daily eLog sugar/insulin 6.7: Support Health Coaches 6.6: Support Physicians 6.6: Support/advice via mail -Lowest (4.6): Homework physical exercise -2 nd Low (5.6): Health Quiz
9. Future Use Intention	All items ≥ 6.1 6.9: Ask advice Health Coaches or Physicians 6.7 Daily eLog sugar/insulin	6.7: Daily eLog sugar/insulin 6.6: Adopt regular training 6.6: Ask advice Health Coaches or Physicians Lowest (5.0): Food/exercise logging in dashboard All other items ≥ 6.0

Table 1: TAM (Technology Acceptance Model) user evaluation summary (n=11, weeks 4 and 12)

The TAM (Technology Acceptance Model, Likert scale 1 to 7, strongly disagree to strongly agree, with several negatively coded items) user evaluation at weeks 4 and 12 shows three patterns. First, these patients were relatively positive at 4 weeks and 12 weeks about all TAM constructs. Aspects that scored particularly high were: usefulness and the support offered by the multidisciplinary health team, and the simple solution for daily logging of sugar/insulin levels.

Besides, some patients were not ICT-literate and clearly had trouble with eTools like the Health Quiz of food/exercise logging. Some (not necessarily the same) patients experienced most challenges in implementing the food and exercise guidelines, fitting them into their daily lives.

Finally, some slight changes over time became apparent. At 4 weeks the main positive points were: support, results monitoring (sugar/insulin) and increased literacy. At 12 weeks the main positive points were: the personal trainers (4th year physiotherapy students who trained the groups 3x per week for 12 weeks), health literacy. The main challenges at week 4 were: Food

guidelines, homework for physical exercise and the health quiz. At 12 weeks, the TAM scores on service mix elements that were experienced as challenging were slightly lower. The food/exercise logging and health quiz become more of an effort for several patients. Also, the homework for physical exercise received a relatively low score (4.6) when evaluating the (e)Support mix (construct 8). Finally, at 12 weeks it became more apparent for some participants that other patients outside the group did not always understand or appreciate the value of this intervention (TAM construct 3: opinion of social circle).

Part of the positive user evaluations regarded the quality of the multidisciplinary support team: health coaches increasing self-efficacy and health literacy, physiotherapy students conducting highly motivating group training sessions for 12 weeks, plus the clinical support team. Given the strong insulin therapy reduction in the first days and weeks (40%-50% reduction on day 1 and about 75% in week 1), close cooperation with the physicians was critical to avoid hypoglycemia in response to the HINTc intervention. Two patients were able to stop medication altogether in this period and were still without insulin medication at the 12-week measurement point. Throughout the 12-week period several medication changes were needed (like lower blood pressure medication), under close supervision of the physicians.

The final set of study results regard the efficacy of the hybrid eSupport mix deployed. Table 2 shows the authors' evaluation using the theory framework of Figure 1.

Health Effectiveness	Coaching Performance	ICT Value Adding
<u>Health Literacy:</u> ++ Much better than the relatively low literacy start. - Some kept falling back into certain old beliefs and coping patterns. <u>Health behaviours:</u> ++ In 12-week intervention. +/- After 12 weeks: More uncertain, plus variance <u>Health outcomes:</u> ++ Biomarkers & medication. <u>Quality of Life:</u> ++ Strong increase.	<u>Promoting health actions:</u> ++ (e)Coach mix promoted strong steps forward. +/- Uncertain after 12 weeks. <u>Supporting self-efficacy:</u> ++ Strongest impact in first weeks, via daily progress monitoring and (e)Coaching reinforcing impacts of health behaviours. <u>Activating intrinsic motivation:</u> ++ Getting results and feeling better.	<u>Motivators, triggers, experience:</u> ++ Daily monitoring & progress feedback on medication, blood sugar, food, exercise. + Sharing each other's progress. +/- Health quiz, start- & week tips: fun for most patients, but not all. <u>Simplicity:</u> ++ Simple daily mail reminder for sugar/insulin inputs. (Some were highly ICT-illiterate.) - Health Quiz and food logging being complex for some. <u>Fit with coach processes:</u> + eTools were integral part of coach processes. +/- Much motivation support still from the coaches, less from tools.

Table 2: Design evaluation on design requirements from Figure 1 (authors' opinions, 5-point scale from - - to ++)

Each column of Table 3 holds a few lessons. First, if we look at the Health Effectiveness of our HINTc approach, we see mixed results. Biologically, there were large effects. And within the first

three weeks these effects became very pronounced within all 11 participants. Hence they were robust despite the large health, education and psychology differences within the group. However, regarding health literacy and self-management competence, large differences were observed: not only at the start, but some of these differences persisted across the 12 weeks. Second, one of our main coaching goals was fostering self-propelling behaviours, beliefs and motivations that continue after the 12 week HINTc intervention period. Some of these goals were met, via results, feeling better (intrinsic motivation), creating new habits, self-efficacy and literacy (understanding behaviour impacts). Third, for the column of ICT Value Adding, we observed large differences between the participants. What all valued was the simple eLogging of daily insulin/sugar values. How well this worked was also a pleasant surprise for the physicians involved. Also the options to ask for help via mail or the dashboard were valued by all. The other tools, like daily/weekly logging of food and exercise, the start and weektips, the microlearning health quiz, were really valued and used by several but not all participants. Lack of ICT literacy and/or time (some patients had very busy schedules, with full time jobs, families and regular training sessions several times per week) played a role here.

5 Discussion and Conclusion

This preliminary analysis has several limitations. First, the study is not finished. The study design was mainly aimed at testing eHealth intervention effects after 12 weeks, but there is also a 50-week follow up measurement planned in Aug 2016 to help assess long term effects. Second, the 12-week data analyses are not complete yet; more biometric and behaviour data analyses still need to be done and are planned for later in the year. Third, regarding external validity, these study results may only apply to motivated individuals, who volunteer for lifestyle training. Fourth, this was only a pilot study with 11 participants.

Still, on the positive side our results (biological, behavioural, TAM) proved relatively robust across the 11 participants, even though they were diverse in background (education, gender, age, insulin medication levels and co-morbidity, health literacy, coping and learning styles). And this pilot provided an opportunity to conduct a design analysis on the hybrid service mix deployed.

5.1 Design Lessons and Implications for Practice

Several lessons can be learned from this study. Two in relation to the HINTc (High Intensity Nutrition, Training and coaching) approach and three in relation to the suitability of hybrid eHealth support.

First, it is interesting to see in this HINTc intervention that satisfaction is high (at 4 weeks) and stays high (for at least 12 weeks), despite the fact that large lifestyle changes are requested from the participants. Our interpretation is that contributing factors for this satisfaction are: gains in self-efficacy and health literacy, seeing results fast and feeling results fast, which activates intrinsic motivation. In other words: the large and growing benefits that patients experience. The benefits, besides medication reduction, are also clearly visible in the rising average scores

on the Physical Health dimension of the SF-8 Quality of Life survey. Second, based on qualitative feedback from the participants, it appears that a number of the new, healthier food and exercise patterns started to become 'the new normal' already after 4 weeks into the intervention.

Third, opinions varied regarding the suitability of most of the eTools provided (like the health quiz, the email weektips, food and exercise logging). In the short term of the first few weeks, virtually all tools were used by virtually all patients. After about 2 to 3 weeks, usage grew for some but declined for others. Two factors appeared important in determining adoption and use of these tools: availability of time, plus ICT literacy (with the latter appearing most important: four participants expressed aversion at using computers).

Fourth, the exception to this varied eTool adoption pattern was the simple, daily mail reminder for sugar/insulin inputs: everybody used it well and wanted to continue using it. It was constructed with the use of a personal, secure link: a simple click was enough to land on the right eDashboard page for sugar and insulin eLogging (however, others would not be able to enter the eDashboard with this link). We think that the combination of high simplicity with high usefulness was the key to its high adoption: this was an important basis for the daily feedback/coaching from the multidisciplinary support team.

Finally, the multidisciplinary support team was highly valued (health coaches increasing self-efficacy and health literacy, physiotherapy students conducting highly motivating group training sessions for 12 weeks, plus the clinical support team). This had two aspects. One: all support team members shared the same view on the patients' progress. Second, the group effects were strong and positive: 'we are all in this together and we support each other.' This fostered high levels of interpersonal commitment, which is something that is harder to achieve with eTools.

5.2 Implications for Theory

One of the most striking observations regarding some of the patients in this group was that their learning styles were highly non-cognitive. An (apparent) understanding of health cause and effect seemed to have less impact than experiencing cause and effect. Sometimes over and over again. Some of them would only consider trying new coping styles after many clear experiences of failure of their old coping styles. Daily feedback loops between behaviours and (negatively high) sugar values were useful in this regard. For this group, learning is not very much about explicit awareness, intentions, goals and behaviour plans (as postulated in models like HAPA and i-change, Schwarzer 2010, Wiedeman 2011). This is in contrast with other participants who were very keen on adopting new coping behaviours as soon as they understood cause and effect: the more cognitive approach.

Summarizing from this study, we can conclude a few key points. First, the intensive training and coaching strongly improved patients' health literacy and quality of life, both supporting healthier behaviours. Second, biologically a virtuous cycle was started, helping patients reverse diabetes-2 progression, lowering all from a toxic level of insulin therapy to on average 79% lower levels, with 2 patients able to stop insulin. Third, this is a challenging patient group with some being

relatively low in health- and ICT literacy. Following the design analysis, the highly simplified solution we created for secure, daily eLogging for sugar/insulin for this group was relatively useful. All patients used it well and it enabled everybody involved to closely monitor progression. Regarding other eTools, appreciation and use varied more, largely depending on ICT literacy and partly depending on time (some patients had very busy schedules, with full time jobs, families and regular training sessions every week).

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